O'CONNELL & ARONOWITZ
ATTORNEYS AT LAW

November 8, 2017

VIA ECF

Hon. Thomas J. McAvoy
U.S. District Judge
U.S. Courthouse
15 Henry Street
Binghamton NY. 13901

Re: American Bio Medica Corp. v. Bailey et al.; Civ. Action No. 1:17-cv-00302-TJM-DJS

Dear Judge McAvoy:

We are counsel to defendants Todd Bailey, April Bailey, Premier Biotech, Inc. and Premier Biotech Labs, LLC ("Premier Defendants"). I am writing with respect to Document 30, a Reply Memorandum of Law ("Reply Memo"), filed on November 2 by plaintiff American Bio Medica Corp. ("ABMC") in further support of its motion for leave to supplement the complaint, which motion was opposed by the Premier Defendants and defendant Peckham Vocational Industries, Inc.'s ("Peckham").

Local Rule 7.1(b)(2) does not permit the filing of reply papers without the Court's prior permission. We do not believe such permission was requested by plaintiff or granted by the Court. Under the circumstances, it is respectfully requested that the Reply Memo be rejected.

Should the Court decide to permit the submission *nunc pro tunc*, we ask that the following be considered in opposition to the only new argument made with respect to the Premier Defendants, which had it been made timely, we would have responded to in our answering papers:

The Reply Memo (at p. 2) attacks as a "misappropriated trade secret" Premier's recall procedure as set forth in the Peckham/Premier contract proposal to Michigan DOC (Doc. No 25-5, Exhibit I). The recall procedure, however, hardly is a trade secret. The U.S. Food and Drug Administration publishes a "guidance" for industry concerning recalls (the "Guidance"). *See* https://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm. The Guidance states as its purpose:

> *This guidance document is intended to provide guidance and instructions to FDA regulated industry for obtaining information to help fulfill the*

> *Agency's plans regarding product recalls. It represents the agency's current thinking on product recalls.* (Emphasis in original.)

The Guidance elaborates on its intention, which is to "...assist those members of industry regulated by the [FDA] in handling all aspects of a product recall, including all corrections and removals. The [Guidance] includes a checklist of documentation and information that FDA utilizes to evaluate, classify, monitor and audit product recalls... This [Guidance] provides more specific recommendations and applies to both mandatory and voluntary recalls of all FDA-regulated products (...including...medical and radiological devices...)."

In other words, every industry subject to FDA regulation (*i.e.*, every bidder here) is provided by the FDA with a framework for handling product recalls. The recall procedure submitted by Peckham/Premier in Doc. 25-5 – which was requested by Michigan – simply conforms to the FDA Guidance, belying the notion that a recall procedure is a trade secret.

Finally, a company will follow its recall standard operating procedure ("SOP") to recall product from the market by sending a registered letter to its customers with the pertinent information as outlined in the FDA Guidance. Moreover, drug testing manufacturers and distributors such as ABMC and Premier frequently provide their SOPs to state governments and other customers (*e.g.*, large employers) who request the same as part of an open bidding process, just like the State of Michigan did here. By virtue of that fact alone, it is obvious that a recall procedure is not a trade secret, the dissemination of which is restricted to certain employees of an issuing company. Here, moreover, the "user" is a governmental entity, and it would seem that a recall procedure, like everything else submitted in response to a request for proposals, is discoverable pursuant to the applicable freedom of information statute. Again, this demonstrates that a recall procedure is not a trade secret.

The remaining portions of the Reply Memo are addressed in the Premier Defendants' previously submitted motion papers.

Respectfully submitted,

O'CONNELL AND ARONOWITZ

By: /s/ *Paul A. Feigenbaum*

Paul A. Feigenbaum

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